

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231,

on January 28, 2002.

By: Jeffrey Gillis

Jeffrey Gillis

PATENT

Atty. Docket No. DX0261K1Q

CN 028008

COPY

RECEIVED

SEP 19 2002

TECH CENTER 1600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Maria-Grazia RONCAROLO, et al.

Serial No.: 09/718,102

Filed: 11/20/00

For: USE OF INTERLEUKIN-10 TO
PRODUCE A POPULATION OF
SUPPRESSOR CELLS

Examiner: not yet assigned

Art Unit: 1762

INFORMATION DISCLOSURE
STATEMENT

Palo Alto, California 94304

January 28, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

COPIED FOR S-P ON
DATE: JAN 28 2002

Sir:

The materials as listed in the attached modified PTO 1449 form are brought to the Examiner's attention pursuant to the duty of disclosure under 37 C.F.R. § 1.56, § 1.97, and § 1.98.

Copies of all references except references AI and BD, have been included in the Information Disclosure Statement for one parent file, U.S.S.N. 08/643,810, filed May 6, 1996, Attorney Docket No. DX0261K1, and should be available there.

Copies of newly cited references AI and BD are attached hereto.

Citation of these documents should not be construed as a representation that the documents are in fact material or are in fact prior art with respect to the instant invention. The Examiner should not make any inference relating to the relative pertinence of cited references based upon the order in which the art is presented. Citation of these documents should not be construed as a representation that a search has been made or that more pertinent art may not be in existence.

Applicants request that the Examiner fully consider the art cited in the attached modified PTO 1449 form. Applicants further request that the Patent and Trademark Office list all such art on the front of any patent issuing from this application.

Since this Information Disclosure Statement is being filed before receiving the first Office action, applicants believe no fee is required for filing this document; however, if such a fee is required the Commissioner is hereby authorized to charge DNAX Research Institute's Deposit Account No. 04-1239.

January 28, 2002

Respectfully submitted,

By: Sheela Mohan-Peterson
Sheela Mohan-Peterson
Attorney for Applicants
Reg. No. 41,201

Enclosures: Modified PTO 1449 form (4 pages)
References AI and BD (2 refs.)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT FOR PATENT (Use several sheets if necessary)	ATTY. DOCKET NO.: DX0261K1Q	SERIAL NO.: 09/718,102
	APPLICANT: Maria-Grazia RONCAROLO, et al.	
	FILING DATE: 11/20/00	GROUP: 1762

U.S. PATENT DOCUMENTS

*EXAMINE R INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
AA	4,483,920	20 Nov 84	Gillespie et al.	435	6	17 May 82
AB	4,559,310	17 Dec 85	Cantor et al.	436	519	20 May 83

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
AC	EP 405 980	2 Jan 91	EP	C12N	15/24	X

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AD	Daniel M. Altman, et al., <i>Nature</i> 338:512-514, April 1989. "Cotransfection of ICAM-1 and HLA-DR Reconstitutes Human Antigen-Presenting Cell Function in Mouse L Cells"
AE	Michel Arock, et al., <i>Eur. J. Immunol.</i> 26:166-170, 1996. "Interleukin-10 Inhibits Cytokine Generation from Mast Cells"
AF	Rosa Bacchetta, et al., <i>J. Immunol.</i> 144:902-908, February 1990. "Host-Reactive CD4+ and CD8+ T Cell Clones Isolated from a Human Chimera Produce IL-5, IL-2, IFN- γ , and Granulocyte Macrophage Colony Stimulating Factor but Not IL-5"
AG	Rosa Bacchetta, et al., <i>J. Exp. Med.</i> 179:493-502, February 1994. "High Levels of Interleukin 10 Production In Vivo Are Associated with Tolerance in SCID Patients Transplanted with HLA Mismatched Hematopoietic Stem Cells"
AH	Rosa Bacchetta, et al., <i>J. Clin. Invest.</i> 91:1067-1078, March 1993. "Chimerism and Tolerance to Host and Donor in Severe Combined Immunodeficiencies Transplanted with Fetal Liver Stem Cells"
AI	J.C. Becker, et al. <i>International Immunology</i> , 6(10):1605-12, 1994. "Maintenance of clonal anergy by endogenously produced IL-10"
AJ	Maria-Teresa Bejarano, et al., <i>Int. J. Cancer</i> 35:327-333, 1985. "Effect of Cyclosporin-A (CsA) on the Ability of T Lymphocytes Subsets to Inhibit the Proliferation of Autologous EBV-Transformed B Cells"
AK	Maria-Teresa Bejarano, et al., <i>Intl. Immunol.</i> 4:1389-1397, September 1992. "Interleukin 10 Inhibits Allogeneic Proliferative and Cytotoxic T Cell Responses Generated in Primary Mixed Lymphocyte Cultures"
AL	Michael Bevan, <i>Immunol. Today</i> 5:128-130, 1984. "High Determinant Density May Explain the Phenomenon of Alloreactivity"
AM	Avilnash Bhandoola, et al., <i>J. Immunol.</i> 151:2355-2367, September 1, 1993. "Reduced CD3-Mediated Protein Tyrosine Phosphorylation in Anergic CD4+ and CD8+ T Cells"
AN	Vassiliki A. Boussiotis, et al., <i>J. Exp. Med.</i> 180:1665-1673, November 1994. "CD2 Is Involved in Maintenance and Reversal of Human Alloantigen-specific Clonal Anergy"
AO	F. Cardillo, et al. <i>European Journal of Immunology</i> , 23:2597-2605, 1993. "An age-related $\gamma\delta$ T cell supressor activity correlates with the outcome of autoimmunity in experimental Trypanosoma cruzi infection"

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED

SEP 19 2002

COPIED FOR S-P ON

DATE: JAN 28 2002

TECH CENTER 1600/2900

FORM PTO-1449 SEP 17 2002 PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT FOR PATENT (Use several sheets if necessary)	ATTY. DOCKET NO.:	SERIAL NO.:
	DX0261K1Q	09/718,102
	APPLICANT:	
	Maria-Grazia RONCAROLO, et al.	
	FILING DATE:	GROUP:
	11/20/00	1762

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AP	Christophe Caux, et al., <u>Int'l. Immunol.</u> 6:1177-1185, 1994. "Interleukin 1 Inhibits T Cell Alloreaction Induced by Human Dendritic Cells"
AQ	Andrew C. Chan, et al., <u>Ann. Rev. Immunol.</u> 12:555-592, 1994. "The Role of Protein Tyrosine Kinases and Protein Tyrosine Phosphatases in T Cell Antigen Receptor Signal Transduction"
AR	Chung-Hsing Chang, et al., <u>Eur. J. Immunol.</u> 25:394-398, 1995. "B7-1 Expression of Langerhans Cells Is Up-Regulated by Proinflammatory Cytokines, and is Down-Regulated by Interferon- γ or by Interleukin-10"
AS	Youchai Chen, et al., <u>Nature</u> , 376:177-180, July 13, 1995. "Peripheral Deletion of Antigen-Reactive T Cells in Oral Tolerance"
AT	Youchai Chen, et al., <u>Science</u> 265:1237-1240, August 26, 1995. "Regulatory T Cell Clones Induced by Oral Tolerance: Suppression of Autoimmune Encephalomyelitis"
AU	F.Q. Cunha, et al., <u>Biochem. Biophys. Res. Comm.</u> 182:1155-1159, February 1992. "Interleukin-10 (IL-10) Inhibits the Induction of Nitric Oxide Synthetase by Interferon- γ in Murine Macrophages"
AV	Annalisa D'Andrea, et al., <u>J. Exp. Med.</u> 178:1041-1048, September 1993. "Interleukin 10 (IL-10) Inhibits Human Lymphocyte Interferon- γ Production by Suppressing Natural Killer Cell Stimulatory Factor/IL-12 Sythesis in Accessory Cells"
AW	Dimuthu R. DeSilva, et al., <u>J. Immunol.</u> 147:3261-3267, November 15, 1991. "Clonal Anergy Is Induced In Vitro by T Cell Receptor Occupancy in the Absence of Proliferation"
AX	Jan E. de Vries, et al., eds., <u>Interleukin-10</u> , R.G. Landes Co., Austin, TX, title page, verso, and table of contents, 1995.
AY	Rene de Waal Malefyt, et al., <u>J. Immunol.</u> 150:4754-4765, June 1, 1993. "Direct Effects of IL-10 on Subsets of Human CD4+ T Cell Clones and Resting T Cells"
AZ	René de Waal Malefyt, et al., <u>J. Exp. Med.</u> 174:915-924, October 1991. "Interleukin 10 (IL-10) and Viral IL-10 Strongly Reduce Antigen-specific Human T Cell Proliferation by Diminishing the Antigen-presenting Capacity of Monocytes via Downregulation of Class II Major Histocompatibility Complex Expression"
BA	Rene de Waal Malefyt, et al., <u>J. Exp. Med.</u> 174:1209-1220, November 1991. "Interleukin 10 (IL-10) Inhibits Cytokine Synthesis by Human Monocytes: An Autoregulatory Role of IL-10 Produced by Monocytes"
BB	Linna Ding, et al., <u>J. Immunol.</u> 151:1224-1234, August 1, 1993. "IL-10 Inhibits Macrophage Costimulatory Activity by Selectively Inhibiting the Up-Regulation of B7 Expression"
BC	Linna Ding, et al., <u>J. Immunol.</u> 148:33133-3139, May 15, 1992. "IL-10 Inhibits Mitogen-Induced T Cell Proliferation by Selectively Inhibitn Macrophage Costimulatory Function"
BD	A. Enk, et al. <u>Journal of Experimental Medicine</u> , 179:1397-1402, 1994. "Induction of Hapten-specific Tolerance by Interleukin 10 In Vivo"
BE	Stephan Fasler, et al., <u>J. Immunol.</u> 155:4199-4206, 1995. "Peptide-Induced Anergy in Allergen-Specific Human Th2 Cells Results in Lack of Cytokine Production and B Cell Help for IgE Synthesis"
BF	Patrick E. Fields, et al., <u>Science</u> 271:1276-1278. "Blocked Ras Activation in Anergic CD4+ T Cells"

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVE

SEP 19 2002

TECH CENTER 1600/

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT FOR PATENT (Use several sheets if necessary)	ATTY. DOCKET NO.:	SERIAL NO.:
	DX0261K1Q	09/718,102
	APPLICANT: Maria-Grazia RONCAROLO, et al.	
	FILING DATE:	GROUP:
	11/20/00	1762

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

BG	David F. Fiorentino, et al., <u>J. Exp. Med.</u> 170:2081-2095, December 1989. "Two Types of Mouse T Helper Cell: IV. Th2 Clones Secrete a Factor that Inhibits Cytokine Production by Th1 Clones"
BH	David F. Fiorentino, et al., <u>J. Immunol.</u> 146:3444-3451, May 1991. "IL-10 Acts on the Antigen-Presenting Cell to Inhibit Cytokine Production by Th1 Cells"
BI	Stephen J. Forman, et al., <u>Bone Marrow Transplantation</u> , Blackwell Scientific Publications, Cambridge, MA, Chapter 4, verso and pp. 37-38, 1994.
BJ	James D. Fraser, et al., <u>Immunol. Today</u> 14:357-362, 1993. "Signal Transduction Events Leading to T-Cell Lymphokine Gene Expression"
BK	Arnold S. Freedman, et al., <u>J. Immunol.</u> 139:3260-3267, November 1987. "B7, a B Cell-Restricted Antigen that Identifies Preactivated B Cells"
BL	Ricardo T. Gazzinelli, et al., <u>J. Immunol.</u> 148:1792-1796, 1992. "IL-10 Inhibits Parasite Killing and Nitrogen Oxide Production by IFN-g-Activated Macrophages"
BM	Ning Fei Go, et al., <u>J. Exp. Med.</u> 172:1625-1631, December 1990. "Interleukin 10, a Novel B Cell Stimulatory Factor: Unresponsiveness of X Chromosome-Linked Immunodeficiency B Cells"
BN	Hervé Groux, et al., <u>J. Exp. Med.</u> 184:19-29, July 1996. "Interleukin-10 Induces a Long-Term Antigen-Specific Anergic State in Human CD4+ T Cells"
BO	Clifford V. Harding, et al., <u>Proc. Natl. Acad. Sci.</u> 87:5553-5557, July 1990. "Functional and Ultrastructural Evidence for Intracellular Formation of Major Histocompatibility Complex Class II-Peptide Complexes during Antigen Processing"
BP	Chyi-Song Hsieh, et al., <u>Science</u> 260:547-549, April 1993. "Development of Th1 CD4+ T Cells through IL-12 Produced by <i>Listeria</i> -Induced Macrophages"
BQ	Di-Hwei Hsu, et al., <u>Science</u> , 250:830-832, Nov. 1990. "Expression of Interleukin-10 Activity by Epstein-Barr Virus Protein BCRF1"
BR	Marc K. Jenkins, <u>Immunol. Today</u> 13:69-73, 1992. "The Role of Cell Division in the Induction of Clonal Anergy"
BS	Marc Jenkins, et al., <u>J. Immunol.</u> 144:16-22, January 1, 1990. "Inhibition of Antigen-Specific Proliferation of Type 1 Murine T Cell Clones after Stimulation with Immobilized Anti-CD3 Monoclonal Antibody"
BT	Sang-Mo Kang, et al., <u>Science</u> 257:1134-1138, August 21, 1992. "Transactivation by AP-1 Is a Molecular Target of T Cell Clonal Anergy"
BU	Jonathan R. Lamb, et al., <u>J. Exp. Med.</u> 157:1434-1447, May 1983. "Induction of Tolerance in Influenza Virus-Immune T Lymphocyte Clones with Synthetic Peptides of Influenza Hemagglutinin"
BV	Wei Li, et al., <u>Science</u> 271:1272-1276, March 1, 1996. "Blocked Signal Transduction to the ERK and JNK Protein Kinases in Anergic CD4+ T Cells"
BW	Steven E. Macatonia, et al., "Differential Effect of IL-10 on Dendritic Cell-Induced T Cell Proliferation and IFN- γ Production" <u>J. Immunol.</u> 150:3755-3765, May 1, 1993.
BX	Keven W. Moore, et al., <u>Science</u> 248:1230-1234, June 1990. "Homology of Cytokine Synthesis Inhibitory Factor (IL-10) to the Epstein-Barr Virus Gene BCRF1"
BY	Hiroaki Niino, et al., <u>Intl. Immunol.</u> 6:661-664, 1994. "IL-10 Inhibits Prostaglandin E2 Production by Lypopolysaccharide-Stimulated Monocytes"
BZ	William E. Paul, ed., <u>Fundamental Immunology</u> , 2nd ed., Raven Press, NY, title page, verso, Chapter 1 pp. 15-16, 1989.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: DX0261K1Q	SERIAL NO.: 09/718,102
INFORMATION DISCLOSURE STATEMENT FOR PATENT (Use several sheets if necessary)				APPLICANT: Maria-Grazia RONCAROLO, et al.	
				FILING DATE: 11/20/00	GROUP: 1762
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
CA	Ligia M. T. Peçanha, et al., <u>J. Immunol.</u> 150:3215-3233, April 15, 1993. "IL-10 Inhibits T Cell-Independent but Not T Cell-Dependent Responses in Vitro"				
CB	Josette Péguet-Navarro, et al., <u>Er. J. Immunol.</u> 24:884-891, 1994. "Interleukin-10 Inhibits the Primary Allogenic T Cell Response to Human Epidermal Langerhans Cells"				
CC	Fred Ramsdell, et al., <u>Science</u> 257:1130-1134, August 21, 1994. "Maintenance of in Vivo Tolerance by Persistence of Antigen"				
CD	Han-Jurgen Rode, et al., <u>Virus Genes</u> 7:111-116, 1993. "The Genome of Equine Herpesvirus Type 2 Harbors an Interleukin 10 (IL-10)-Like Gene"				
CE	Maria-Grazia Roncarolo, et al., <u>Bone Marrow Transplantation: Proceedings of Fetal and Neonatal Cell Transplantation and Retroviral Gene Therapy</u> , Vol. 9, Supp. 1:127-128, 1992. "T Cell Repertoire and Tolerance After Fetal Stem Cell Transplantation"				
CF	Maria-Grazia Roncarolo, et al., <u>Journal of Cellular Biochemistry</u> , supp. 16A:214, 1992. "SCID Patients Reconstituted by Fetal Liver Stem Cells: Possible Role of IL-10 in Transplantation Tolerance"				
CG	Maria Grazia Roncarolo, et al., <u>J. Exp. Med.</u> 167:1523-1534, May 1988. "Alloreactive T Cell Clones Specific for Class I and Class II HLA Antigens Isoated from a Human Chimera"				
CH	Ronald H. Schwartz, <u>Science</u> 248:1349-1356, June 15, 1990. "A Cell Culture Model for T Lymphocyte Clonal Anergy"				
CI	Hergen Spits, et al., <u>Int. Arch. Allergy Immunol.</u> 99:8-15, 1992. "Functional Characterization of Human IL-10"				
CJ	Gen Suzuki, et al., <u>Int'l. Immunol.</u> 7:37-43, 1995. "Impaired CD-28-Mediated Co-Stimulation in Anergic T Cells"				
CK	Kazuyuki Taga, et al., <u>Blood</u> 81:2964-2971, June 1, 1993. "Human Interleukin-10 Can Directly Inhibit T-Cell Growth"				
CL	Shingo Takanaski, et al., <u>J. Exp. Med.</u> 180:711-715, August 1994. "Interleukin 10 Inhibits Lipopolysaccharide-Induced Survival and Cytokine Production by Human Peripheral Blood Eosinophils"				
CM	Bart A. E. Vandekerckhove, et al., <u>J. Exp. Med.</u> 175:1033-1043, April 1992. "Human Hematopoietic Cells and Thymic Epithelial Cells Induce Tolerance via Different Mechanisms in the SCID-hu Mouse Thymus"				
CN	P. Vieira, et al., <u>Proc. Natl. Acad. Sci.</u> 88:1172-1176, Feb. 1991. "Isolation and Expression of Human Cytokine Synthesis Inhibitory Factor cDNA Clones: Homology to Epstein-Barr Virus Open reading Frame BCRF1"				
CO	R. Weimer, et al. <u>Transplantation</u> , 62(11):1606-1614, 1996. "Pretransplant CD4 Helper Function and Interleukin 10 Response Predict Risk of Acute Kidney Graft Rejection"				
CP	Fabienne Williams, et al., <u>Eur. J. Immunol.</u> 24:1007-1009, 1994. "Interleukin-10 Inhibits B7 and Intercellular Adhesion Molecule-1 Expression on Human Monocytes"				
CQ	Hans Yssel, et al., <u>J. Immunol.</u> 149:2378-2384, October 1, 1992. "IL-10 Is Produced by Subsets of Human CD4+ T Cell Clones and Peripheral Blood T Cells"				
EXAMINER				DATE CONSIDERED	
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>					

RECEIVED

SEP 19 2002

TECH CENTER 1600/2